

## WHAT IS CLAIMED IS

- [c1]1. An isolated complex comprising one or both of complement activation product C5, and membrane attack complex (C5b-9) associated with CIC.
- [c2]2. A method for inhibiting the formation of a non-covalent combination of MAC and CIC comprising application of an inhibitor selected from the group consisting of a monoclonal antibody, peptide mimotope, or small molecule in patients suffering from complement and CIC mediated diseases, including but not limited to SLE, RA, cardiovascular diseases, kidney diseases, and autoimmune diseases.
- [c3]3. A method for screening candidate compositions or processes for inhibiting the formation of MAC on CIC comprising assessing the composition or process for the reduction in MAC associated with CIC as a result of the application of the candidate composition or process.
- [c4]4. The use of monitoring or measuring the formation of MAC and other split products of C5 on CIC from the serum, plasma, cerebrospinal fluid and other bodily fluids in diseases associated with complement and CIC pathogenesis, including but not limited to autoimmune diseases, cardiovascular diseases, neurodegenerative diseases, infectious disease and oncological diseases.
- [c5]5. Isolated complexes comprising one or more of the group consisting of non-covalent linked complement split products C1q, C3, C4, C5 and MAC on CIC.
- [c6]6. A method of inhibiting non-covalent association of C1q, C3, C4, C5 and MAC to CIC comprising application of an inhibitor selected from the group consisting of a monoclonal antibody, peptide mimotope, or small molecule in patients suffering from complement and CIC mediated diseases, including but not limited to SLE, RA, cardiovascular diseases, kidney diseases, and autoimmune diseases.

- [c7]7. Screening or designing a useful composition for blocking the formation of MAC on CIC as claimed in claim 6.
- [c8]8. The usefulness of monitoring the complement split products C1q, C3, C4, C5 and MAC on CIC as claimed in claim 5, for diagnosis and monitoring the disease activity in diseases pathogenicity associated with complement and CIC pathogenesis including but not limited to autoimmune diseases, cardiovascular diseases, neurodegenerative diseases, infectious disease and oncological diseases.
- [c9]9. A process for quantitative measurement for the presence of complement C5 and C5b-9 associated with CIC, the process comprising the following steps:
- a. Providing a test device comprising a receptor preparation in solid phase as a capture reagent for CIC;
  - b. Establishing a selected working range for an immunoassay within said ranges of composition of CIC, IgG-CIC 2 to 1000 µg/ml, IgA-CIC 0 to 1000µg/ml, IgM-CIC 0 to µg/ml, C1q bound to CIC 0 to 10 µg/ml, C3 bound to CIC 0 to 30 µg/ml, C4 bound to CIC 0 to 10 µg/ml, C5 bound to CIC 0 to 10 µg/ml and C5b-9 0 to 10 µg/ml;.
  - c. Constructing a standard assay curve by plotting relative degree of immunochemical binding of said CIC components to the test device;
  - d. Interacting a fixed concentration of immunospecific conjugate of said substances, the composition of complexes resulting from said immunological substances and immunospecific conjugate being within the selected working range limits;
  - e. Providing a test system comprising of said test device, said immunospecific conjugate, said immunological substances, the amount of said immunospecific conjugate being substantially equivalent to said fixed concentration of immunospecific conjugate, and the amount of said immunospecifically determinable substance being appropriate to produce a known degree of immunochemical binding corresponding to a pre determined point on said standard curve, thereby enabling quantitative assaying of one or more of complement proteins C1q, C3, C4, C5 and C5b-9 present on CIC.

[c10]10. The use of monitoring the complement proteins C1q, C3, C4, C5 and C5b-9 bound via non covalent binding to CIC for diagnosis or monitoring of disease activity in humans suffering with complement and CIC mediated injuries including but not limited to autoimmune, cardiovascular, neurodegenerative disorders, oncological diseases and infectious disease.

[c11]11. A process for measurement of one or more complement proteins C1q, C3, C4, C5 and C5b-9 from plasma or other bodily fluids of animals suffering from or at risk of suffering from a disease or condition, including but not limited to autoimmune, cardiovascular, neurodegenerative disorders, oncological diseases and infectious disease, said process comprising:

- a. Providing a test device comprising a receptor preparation in solid phase ;
- b. Establishing selected working ranges for said immunoassay within said ranges for complement proteins;
- c. Constructing a standard assay curve by plotting relative degree of immunochemical binding of said complement component(s) to the test device;
- d. Interacting a fixed concentration of a immunospecific conjugate directed to complement proteins and immunospecific conjugate being within pre selected working range limits;
- e. Providing a test system comprising of said test device, said immunospecific conjugate, said immunological substances, the amount of said immunospecific conjugate being substantially equivalent to said fixed concentration of immunospecific conjugate, and the amount of said immunospecifically determinable substance being appropriate to produce a known degree of immunochemical binding corresponding to a pre determined point on said standard curve, thereby enabling quantitative assaying of one or more of complement C1q, C3, C4, C5 and C5b-9 present on CIC.

[c12]12. A process for quantitation of immunoglobulin isotype composition of CIC or antigens bound within CIC comprising using an ELISA based on receptor based capture mechanism, said process comprising:

- a. Placing the receptor on solid phase of ELISA plates, micro beads or other suitable surface;
- b. Attaching the biotin or other form of detection tag on the antigen or antibody;
- c. Mixing the tagged antigen or antibody with the patient plasma, patient serum, sinuovial fluid, cerebrospinal fluid (CSF) or other bodily fluid;
- d. Placing the mixture in contact with receptor attached to the solid surface;
- e. Washing the unbound components with buffers;
- f. Quantitating the tagged antigen or antibody with a reagent including, but not limited to Avidin-Horse Radish Peroxidase and color development reagents.

[c13]13. A process as set forth in claim 3 for screening the composition of a blocking agent for the formation of MAC and deposition of C5 on CIC.

[c14]14. A process as set forth in claim 8 for screening of the composition of a blocking agent for blocking the association of split products C1q, C3, C4, C5 and MAC to CIC as set forth in claim 6 to achieve beneficial therapeutic affects in complement and CIC mediated diseases.

[c15]15. A process for screening a composition that targets blocking of complement activation or other component assembly in the CIC as set forth in claims 11 and 12, and modulating the binding of serum acute phase proteins bound to CIC, said process comprising:

- a. Attaching the receptor to solid phase or studying the interaction in the liquid phase, allowing the interaction of the CIC with the receptor in presence of complement proteins to activate complement deposition or other acute phase proteins on CIC;
- b. Placing the blocking composition during the activation of the complement on CIC or association of serum acute phase protein;
- c. The composition being selected from the group consisting of a chemical, biochemical, protein, peptide and monoclonal ;
- d. Obtaining initial data indicating whether the formation of MAC and binding of complement C1q, C2, C3, C4, and C5 is inhibited on the CIC;
- e. Obtaining data indicating whether the serum acute phase proteins associated with the CIC is inhibited.

[c16]16. A process for determining the extent of blocking of complement activation on CIC, said process comprising:

- a. Attaching the receptor to solid phase or studying the interaction in the liquid phase, allowing the interaction of the receptor with the serum or plasma of patients suffering from complement and CIC mediated injuries to study activated complement deposited on CIC
- b. Placing the blocking composition during the interaction of the receptor or disease plasma or serum
- c. The composition could be a chemical, biochemical, protein, peptide and monoclonal antibody prepared by any technique known to people in the art.
- d. Obtaining initial data indicating whether the MAC or complement activation product C1q, C2, C3, C4 and C5 on CIC are reduced by composition in claim 7d on the CIC.
- e. Obtaining initial data whether the serum acute phase proteins associated with CIC are reduced by composition in claim 9e

[c17]17. The composition of claim 13 or 14, wherein said composition is used for obtaining beneficial therapeutic outcome in diseases or conditions including but not limited to infections, cardiovascular diseases, neurodegenerative diseases, renal disease, rheumatologic diseases, neoplastic disease, and transplant in human patients.

[c18]18. A method of reducing disease symptoms in an individual comprising:  
identifying an individual in need of reducing the symptoms due to increased complement fixation on CIC leading to inflammation and tissue necrosis by administering a composition comprising a monoclonal antibody, peptide, mimotope or active molecule

[c19]19. A process in accordance with claim 11 or 12 that further comprises contacting a receptor during interaction with CIC and complement with at least one of a humanized monoclonal antibodies, active molecules, peptides and

mimotopes and obtaining data indicative of whether the activation of complement has been inhibited.

[c20]20. A process in accordance with claim 17 that further comprises inoculating patients or animals with the immune complex and composition, wherein the immune complex mediated immune responses are altered providing beneficial effect